

**Office of Management and Budget
Supporting Statement
for the
Patient Centered Care Collaboration to Improve Minority
Health Initiative**

July 2011

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ATTACHMENTS

Attachment 1: Evaluation and Data Source Table

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Draft
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Patient Centered Care Collaboration to Improve Minority
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Supporting Statement Abstract. Within the Department of Health and Human Services, the Office of Minority Health, a staff office to the Office of the Secretary, serves as the focal point of leadership, policy development and coordination, service demonstration, information exchange, coalition and partnership building, and related efforts to address health needs of racial and ethnic minorities. This data collection is for the Office of Minority Health’s Patient Centered Care Collaboration to Improve Minority Health Initiative, a project that addresses the needs of these racial and ethnic minority populations. The study will explore the effect that the dissemination of two patient centered outcomes research evidenced based practices/interventions have on patients for improving their health and well being, on the likelihood of changing their behaviors and managing their health to improve their health status.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Office of Minority Health (OMH) in the Office of the Assistant Secretary for Health (OASH), Office of the Secretary (OS) is requesting approval from the Office of Management and Budget (OMB) for new data collection activities for the Patient Centered Care Collaboration to Improve Minority Health project (PCCC). The purpose of this data collection activity is to determine if:

- disseminating a diabetes education intervention in a community based health clinic and offering a medication management and adherence intervention through home visits to seniors, improves the health and well being of racial and ethnic minority program participants;
- the approach taken through the implementation of proven patient centered outcomes research (PCOR) findings such as using community health workers and educators, and pharmacists to deliver the

interventions improves the likelihood of patients changing their behaviors to improve their health status; and

- participants learned new information and skills that would help them to manage their health conditions and improve their health status.

The PCCC Project Overview. The PCCC will offer interventions based on evidence based research findings that have been tested on racial and ethnic minorities and proven to be effective practices/interventions for improving specific health conditions. The interventions will be implemented as a dissemination strategy to increase awareness and change behaviors in communities faced with health disparity challenges. The desire is for these residents of these communities to be receptive to new and proven practices for changing behaviors. And, that they will ultimately adopt and use them in the management of their health care. The focus will be on patients who could benefit from these approaches to health care. The PCCC project will be implemented in two urban cities, Chicago, Illinois and Houston, Texas.

The Evidenced-based Intervention in Chicago and the Need for Data: Health Empowerment Lifestyle Program (HELP). HELP, a spinoff of the Diabetes Empowerment Education Program (DEEP), focuses on diabetes self-management and control. HELP's learning objectives are to: identify risk factors and ways to prevent them; and understand disease and impact on the body, the numbers (e.g., A1C, blood pressure) associated with the disease, benefits of monitoring, diet, physical activity, medication, and cultural differences associated with diabetes, and hypertension and obesity. PCOR strategies utilized in HELP are: telephone reminders/boosters regarding activities, use of ethnic based physical activities, and use of community health workers (CHW) to recruit patients. HELP is a 12- week program that includes 2 sessions for data collection. There are group sessions of no more than 15 patients per class, weekly interactive 2-hour long sessions, weekly telephone reinforcement/follow-up, and classes are offered in English or Spanish language proficiency. The sample size for this project is: 25 African Americans and 25 Latinos from the Lawndale Christian Health Center (LCHC). A screening tool will be used to determine program eligibility and program data will be collected through in-person interviews by the CHW/trainer at week 1 for baseline and week 12 for the post-intervention.

The selection criteria, for inclusion are: African Americans or Latinos; overweight or obese (BMI > 25) and Type 2 diabetes (Hb1A1c > 7.5) or hypertension; 18 to 65 years of age; non pregnant; ability to perform self care; not travelling during the intervention period; and male or female. The selection criteria for exclusion are: psychiatric diagnoses, alcohol or

substance abuse, seizures, myocardial infarction or stroke within past 6 months, terminal illness, pregnancy, and cognitive impairment.

Patients will be randomly selected from a list of eligible patients from the clinic's database based on having uncontrolled diabetes (Hb1A1c > 7.5); and they will be offered participation in the health education classes. Patients will be recruited by primary care specialists, CHWs, health educators, and case managers. Clinic staff will administer the paper and pencil tools to patients; clinic staff will followup and further discuss the program with the patients and obtain additional eligibility requirements.

Once a patient is deemed eligible and agrees to participate in the program, clinic staff will ensure that they have the patient's electronic health record. CHWs and clinic staff will first have the patients sign a consent form. The forms will be available in Spanish and English, and those who have literacy problems will be offered assistance in completing the form. Unique participant identification numbers, case numbers, will be used to facilitate matching baseline and post-intervention data, but no identifying information will be provided to staff.

The instruments and data collection procedures (see Attachment 2 for the data collection tools) are described here.

- Consent Form—This form will inform the patient of the study, and allow them to acknowledge their participation in the program and consent to complete program questionnaires and have their clinical data - HbA1c, blood pressure, weight, and height available to the program.
- Screening Questionnaire—This questionnaire will be used to determine program eligibility.
- Baseline Questionnaire-Chronic Disease—This questionnaire captures the baseline knowledge, attitude, and behavior/behavioral intentions data; and HbA1c/blood sugar, blood pressure, weight, and waist circumference.
- Post-Intervention Questionnaire—This questionnaire captures the post-intervention knowledge, attitude, and behavior/behavioral intentions data; and HbA1c/blood sugar, blood pressure, weight, and waist circumference.

The Evidenced-based Intervention in Houston and the Need for Data Houston: Medication Adherence.

The focus of this intervention is medication management for patients with hypertension and diabetes. The intervention is based on a Patient Centered Medical Home (PCMH) model where providers partner with patients to improve health outcomes. The learning objectives are to: teach patients medication management, and self-management. The intervention will be delivered by pharmacists (who will be trained by Harris County Hospital District health educators in motivational interviewing and cultural competency). The pharmaceutical care medication

management approach includes a medication assessment, development of a care plan, and follow-up. Licensed pharmacists make residential visits to patients in their senior residential building and provide telephone follow-ups. Health educators, with the support of the pharmacists, provide educational sessions for seniors. PCOR strategies utilized in this intervention include: provider home visits, group health education classes, individual, provider driven telephone calls. The sessions are (dosage): 1 hour home visit conducted by a Pharmacist, 2 monthly health education group classes for 60 minutes each at each facility taught by health educators, 2 reminder phone calls/1 consultation provided 1 to 2 weeks after both educational sessions, and the total study time is less than 5 hours over a 3 month period. Sessions and materials will be tailored to the culture and language of participants. Data will be collected through in-person interviews and telephone interviews at three points. Project staff will collect baseline data in month 1, pharmacists will conduct telephone follow-ups in months 2 and 3, and pharmacists will collect post-intervention data at the end of month 3 of a 3-month intervention program. Incentives provided to patients are: health promotion items given during the educational classes and \$15 store gift card upon completion of the program.

The organizations partnering with Houston and the target populations and health conditions they provide are: Houston Housing Authority Senior Living Facilities, Texas Southern University College of Pharmacy and Health Sciences, and Harris County Hospital District. Patients will be recruited from four of the City of Houston Housing Authority senior independent living facilities. Local hub staff and pharmacy students will visit the four buildings to inform residents of the program and identify eligible patients. The racial/ethnic target populations of the four facilities are as follows: African Americans (n=351), Asian Americans (n=173), Hispanics/Latinos (n=149). The health conditions included are diabetes and hypertension; and the focus is on patients who are 55 years and older and take at least 1 medication.

The selection criteria, for inclusion are as follows: Diabetes: Age 55 years & older, member of target ethnic groups, resident of 1 of the participating facility, taking at least 1 medication for diabetes at time of recruitment, access to a telephone at home; and Hypertension: Age 55 years & older, member of target ethnic groups, resident of 1 of the participating facility, taking at least 1 medication for hypertension at time of recruitment, access to a telephone at home.

Houston Hub staff will first have the patients sign a consent form to acknowledge their participation in the program and consent to complete program questionnaires, as well as consent to have their clinical data (blood pressure readings, measure diabetic HbA1C levels, and weigh patients) measured.

The paper and pencil data collection forms will be administered and completed by the pharmacists and Houston Hub staff, where indicated. The forms will be available in English, Spanish, Chinese, and Vietnamese. Pharmacists and staff will administer the forms in the preferred language of the patient. Unique patient identification numbers will be used to facilitate matching baseline and post-intervention data, but no identifying information will be provided to project staff. Paper forms will be given to project staff for data entry and analysis. Completed questionnaires will be kept in a locked file and the computer database will be password enabled so that only project staff can access the information.

The instruments and data collection procedures (see Attachment 3 for the data collection tools) are described here. Clinical data will be captured by the pharmacists who are trained to take blood pressure readings, measure diabetic HbA1C levels, and weigh patients. Since the patients are not directly linked to a health facility for this project, we will not obtain electronic medical records for the clinical data. Houston will use the following tools:

- Eligibility Screening Form: Hypertension and Diabetes administered during recruitment phase by project staff
- First Home Visit Form for Diabetes (same form for patients with Hypertension and for patients with Diabetes and Hypertension, one form will be administered depending on the health status of the participant). The form that the pharmacist will use during the initial home visit will be guided by the patient's condition. This questionnaire will capture the baseline knowledge, attitude, and behavior/behavioral intentions data.
- Telephone Follow-Up Being Active and Managing Stress (month 1 only) and Telephone Follow-Up: Health Eating (month 2 only). These are administered by the pharmacists following each monthly educational session.
- Post-Intervention Follow-Up Form for Diabetes (same form for patients with Hypertension and for patients with Diabetes and Hypertension, one form will be administered depending on the health status of the participant). This data will be collected two weeks following the final follow-up call by the pharmacist. This questionnaire will capture the post-intervention knowledge, attitude, and behavior/behavioral intentions data as well as clinical indicators (HbA1c, blood pressure, weight, Height). It will be administered by the Houston Hub staff.

Evaluation Questions. The PCCC project will explore these questions: can disseminating community based interventions (a diabetes intervention in a community based health clinic and a medication management and adherence intervention through home visits to seniors) improve racial and ethnic minority participants' health? Can the use of PCOR findings in community based interventions promote behavior changes in program

participants? And, can the relaying of information and increased knowledge help participants to better manage their health conditions? See Attachment 1 for a table of the evaluation questions, data sources and collection time frames.

Administrative Requirements of the Collection. OMH advises components of HHS on health issues important to racial and ethnic minority populations, and carries out targeted initiatives, such as the PCCC, to facilitate this advisory role. Funding for the OMH PCCC is derived from the American Recovery and Reinvestment Act which authorized funds for the establishment of the HHS federal adoption and dissemination program within the Agency for Health Care Quality and Research (AHRQ), and is administered by the Office of the Assistant Secretary for Policy and Evaluation (ASPE). Under this program, AHRQ and ASPE require that federal divisions and agencies participating in this program utilize existing or create new measurement systems to track adoption and adherence rates (measure changes) associated with their proposed CER adoption initiative, and measure health outcomes if possible. In addition, with respect to Congress, the Federal Coordinating Council on CER identified the development, expansion, and use of a variety of data sources and methods as important to assessing CER and to its dissemination of those results. This project serves to evaluate the adoption and dissemination activities called for by the Federal Coordinating Council on CER.

2. Purpose and Use of Information Collection

The purpose of the information is for OMH to answer the question: did the PCCC develop effective dissemination strategies that promoted adoption of PCOR in the two participating communities of Chicago and Houston? Project results are intended to provide guidance to: OMH, the community of health care providers (especially those who serve racial and ethnic minority patients), and community based organizations, that focus on improving the health status of racial and ethnic minority people, on how to inform others of PCOR findings and how to put these findings into practice. OMH will in turn share what is learned from this project with potential users of the evidenced based practices/intervention and how to use a community-based participatory approach for spreading PCOR findings in racial and ethnic minority communities.

The patient data collection tools will yield information on their views of the dissemination strategies, what their attitudes and behaviors are about changing their health status, self management, and knowledge of their health condition. The information will tell us if they adopted the evidenced based practice/intervention by completing the program and instituting what

they learned into their behavioral patterns and were more informed of the techniques to improve their health status.

3. Use of Improved Information Technology and Burden Reduction

Using information technology is a primary consideration for reducing burden when collecting data. If the data are available electronically or can be collected using technology, this is given full consideration as the primary method for obtaining the information. For this project, information technology will be used where available and where feasible to reduce the burden associated with data collection.

In Chicago, the patient's clinical information (HbA1c, blood pressure, and weight) will be retrieved from their electronic medical records (EMR) at the participating health clinic. Obtaining information from the EMR will reduce the burden for staff in retrieving the patient's clinical data. This strategy also reduces opportunity for errors and therefore, improves data quality. In Houston, these data are not available to this project electronically. The patient's clinical information will be obtained by the pharmacist since there is no direct link to the patient's health care provider or to their medical record, electronic or paper.

Chicago and Houston will collect the remaining participant information on knowledge, attitudes, behaviors, and use of PCOR findings using paper and pencil forms. This project will follow already established procedures for data collection at each site. Doing so will facilitate collection activities in Chicago and Houston and keep the burden to a minimum. This will also avoid the need to train staff on another data collection modality or procedure and will avoid any disruption of existing practices. A change in procedures could be costly for the community based operations.

Data collection forms will be completed at the local sites and sent to Westat to enter into a database. No participant identifying information will be sent to Westat. All forms will be de-identified at the local sites and a client identification code will be used on the forms. Westat will use data quality control procedures to check the data before incorporating it into the database. With built-in data quality checks, easy access to data outputs and reports, restricted users of the data can be confident about the quality of the output. The system allows for easy uploading of the data and reporting to those project staff who have access to the database. Levels of access have been defined for users based on their authority and responsibilities regarding the data and reports. Access is limited to those individuals who have a need for the information.

4. Effort to Identify Duplication and Use of Similar Information

The literature review conducted for this project did not identify any studies that were identical to this one. There is no duplication or other similar information available for this project, therefore, no data are available to respond to the evaluation questions posed for this project. The evidence based practice/interventions implemented have not previously been implemented in Chicago and Houston as they are specifically defined for this project.

5. Impact on Small Businesses or Other Small Entities

This data collection activity does not involve small businesses or small entities.

6. Consequences of Collecting the Information Less Frequently

We propose to collect data at two time points for the Chicago program and three for the Houston program. A minimum of two points is required to assess change; collection at one time point is not a valid option. Data collected less frequently will not allow for an exploration of differences, between pre and post, due to the intervention. These collection points will allow us to answer the questions posed for this project and help to demonstrate that the interventions can be successfully implemented in these cities.

The Chicago program will collect data at two time points: baseline and post-intervention, these times are routine data collection points for most intervention programs. Data will be collected at week 1 and week 12.

The Houston program will collect data at three time points due to the nature of the intervention: baseline, telephone follow-up, and post-intervention. These are typical data collection points for most intervention programs designed with a booster, a telephone follow-up, as a part of the intervention design.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection fully complies with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice/Outside Consultation

The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on September 23, 2011 (FR Vol. 76, No. 185: 59130). No comments were received in response to this notice.

9. Explanation of any Payment/Gift to Respondents

Based on their experiences of implementing a similar program, with similar participants, the Chicago hub site will not provide an incentive to the patients. Retention of the participants has been high in previously delivered intervention programs. Participants have been sufficiently motivated to continue with the intervention and complete any post-intervention data collection activities. Based on their history with this program, they indicate that an incentive is not needed 1) to maintain program retention and 2) for a high response rate for the post-intervention survey.

Based on their experiences working with the study population, the Houston site will provide a \$15 gift card for a local store to participants who complete the post-intervention interview. They indicate that this incentive is needed to encourage the patients to complete the survey; this is a customary practice in the field. Their experiences have indicated that the participants may not be sufficiently motivated to complete the post-intervention interview without an incentive.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality is of critical importance to this project. In addition, concern for the protection of participant's rights is key. When the patients enroll in the evidenced based practice/intervention and attend the first session, they will be given a description of the project, the intervention, the data collection activities, and asked to give their consent to participate at that time (see Attachments 4 & 5 for sample consent forms). This information will also let the patients know that their participation is voluntary and if they refuse to

answer the survey questions that they can still continue with the intervention; and that this project involves collection of clinical data.

Since data will be collected at multiple points, it will require using personal identifiers to link the data. Hence, in compliance with the Regulations for the Protection of Human Subjects, the data collection effort has been reviewed and approved by Westat's Institutional Review Board (IRB), and by the IRB's affiliated with the Chicago, Illinois (University of Illinois at Chicago) and Houston, Texas (Texas Southern University) sites. (See Appendix 3 for the IRB approval letter.)

The Health Educators/Community Health Workers (trainers and staff in Chicago; and trainers, staff, and Pharmacists in Houston) will ensure that all data collection tools will use a unique project identification number for each patient. The key for this identifier will only be available at the local project site and will be kept separately from the patient identification numbers. Data will be stored securely at each site and access will only be given to trained staff on an as required basis. OMH and its contractors will not receive identifiable patient records. Patient-level information will be aggregated to, at the least, the level of the local community site.

The local project sites and all potential respondents will be assured that confidentiality is maintained throughout data collection (to the extent permitted by law). All data will be closely safeguarded, and no institutional or individual identifiers will be used in reports. Only aggregated data will be reported.

Westat staff are required to complete training on data confidentiality and security, and issues associated with research involving human subjects on an annual basis. All staff are familiar with the requirements of maintaining confidentiality and the importance of this for patients.

11. Justification for Sensitive Questions

OMH's mission is to improve the health of racial and ethnic minority populations through the development of dissemination strategies that promote the awareness and use of evidenced based practices/interventions to reduce health disparities. A limited number of sensitive items, clinical information, will be collected. These items are routinely collected in health programs, they are: systolic blood pressure, A1C hemoglobin, cholesterol, and weight. These items are essential to the health intervention. Sites will use informed consent forms as required and as viewed appropriate by their individual organizations (see Attachments 4 &5 for sample consent forms). Participant data are routinely collected and subject to the Federal

Regulations on Human Subject Protection (45 CFR Part 46; OMB No. 0925-0404).

12. Estimates of Annualized Hour

Each local hub (Chicago and Houston) will collect data from patients at a baseline and post-intervention; and telephone follow-up in Houston. The times estimated to complete each survey, the estimated hour burden, and cost are provided in Exhibit 1.

Exhibit 1. Estimated Annualized Burden Hours

Respondent Type	Number of Respondents	Responses Per Respondent	Total Responses	Hours Per Response	Total Hour Burden	Hourly Wage	Total Hour Cost / Respondent^{1,2}
Chicago							
Screening Questionnaire	165	1	165	5/60	14	\$15.95	\$224
Intake Questionnaire HELP	50	1	50	40/60	33.0	\$15.95	\$528
Post-Intervention Questionnaire	40	1	40	40/60	27	\$15.95	\$432
Sub-total			255		74	\$15.95	\$1184
Houston							
Eligibility Screening Form 1: Hypertension and Diabetes	200	1	200	15/60	50	\$7.33	\$367
First Home Visit Form: Diabetes or Hypertension or Hypertension and Diabetes	200	1	200	40/60	133	\$7.33	\$975
Telephone Follow-Up: Being Active and Managing Stress	180	1	180	20/60	60	\$7.33	\$440
Telephone Follow-Up: Healthy Eating	180	1	180	20/60	60	\$7.33	\$440
Post Intervention: Diabetes or Hypertension or Hypertension and Diabetes	180	1	180	20/60	60	\$7.33	\$440
Sub-total					363		\$2662

Grand Total	1195			437	\$3846
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NOTES:

¹ Adult estimate based on Bureau of Labor Statistics May 2009 National Occupational Employment and Wage Estimates United States, median hourly wage:
http://www.bls.gov/oes/current/oes_nat.htm#00-0000

Elderly estimate based on food stamp eligibility:
<http://www.foodstampguide.org/gross-and-net-monthly-income-eligibility-standards/>

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers/Capital Costs

The only cost to respondents is their time to complete the surveys. There are neither capital, startup costs, nor operation or maintenance costs.

14. Annualized Cost to Federal Government

The principal additional cost to the government for this project is the cost of a contract to collect the data from the various local hub sites and to conduct analyses and reports from the data collected. The reports examine baseline characteristics as well as the changes between baseline and post-intervention.

The estimated annualized cost for a contract for the PCCC is \$996,500 and the PCCC evaluation effort is approximately \$165,000. Total annual cost to the Federal Government is \$1,161,500.00

15. Explanation for Program Changes or Adjustments

This is a new project.

16. Plans for Tabulation and Publication and Project Time Schedule

The general timeframe is as follows:

- Dissemination strategies will be developed by June 30, 2011
- The intervention implementation is scheduled to begin January 2012 and end in March.
- The baseline data collection is scheduled to begin January 2011.

Data for the PCCC evaluation is needed by OMH prior to the end of the contract, June 2012, in order to conduct the analysis and generate a report. The report will satisfy ARRA funding reporting requirements.

Analysis. Baseline level analysis involves using frequency distributions and measures of central tendency to describe the populations across the patients, and by various demographic groups (e.g., gender, race, ethnicity, age, health status, and level of education).

The patients will be followed and the PCCC outcome items will be re-administered again at post-intervention. The post-intervention data also will be described using frequency distributions and measures of central tendency. Change will be addressed by comparing the post-intervention measurements with baseline data for each patient. The percent of patients showing changes will be calculated on each outcome measure that is categorical. For continuous items, mean differences will be calculated. Tables will be constructed to describe the change across projects on client outcomes.

The PCCC dataset will consist of each element coded into the reporting categories to answer the evaluation questions. These data are at the participant level. The participant data will be aggregated by demographic characteristics of patients and health conditions.

Publication Plans. The analysis will be driven by the evaluation questions, number of patients available to participate in the project (or in some sites the population of patients in the intervention), and the timeframe and resources available.

Participant data will be used to prepare an evaluation report for OMH, AHRQ, and ASPE regarding the results of the PCCC project. This report will include an assessment of the dissemination strategies for patients. OMH may also use the data for:

- Making Federal policy decisions
- Sharing with community-based organizations on the feasibility of implementing PCOR interventions in their communities
- Sharing with health care organizations about the feasibility of implementing PCOR interventions at their sites
- Sharing the data with other Federal agencies whose goals include the reduction of health disparities
- Determining what dissemination strategies are useful for sharing information on PCOR to racial and ethnic minority patients
- Determining what PCOR findings are effective for changing patient behaviors to better manage their health conditions and improve their health status.

17. Reason(s) Display of OMB Expiration Date in Inappropriate/Display of Expiration Date

The expiration date for OMB approval will be displayed on all data collection instruments for which approval is being sought.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions.